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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/595,241	03/29/2006	Chris T. Zimmerle	38484-166	5394

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SIEMENS CORPORATION
INTELLECTUAL PROPERTY DEPARTMENT
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EXAMINER	
GEISEL, KARA E	

ART UNIT	PAPER NUMBER
2877	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/595,241	ZIMMERLE, CHRIS T.	
	Examiner	Art Unit	
	KARA E. GEISEL	2877	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 March 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *29 March 2006* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *0507, 0608*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

The information disclosure statements filed May 18th, 2007 and June 3rd, 2008 have been considered by the examiner.

Drawings

The drawings are objected to because fig. 1 is too dark and the parts of the figure can not be seen. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Objections

Claims 5-6 and 12-13 are objected to because of the following informalities:

In regards to claims 5-6 and 12-13 "the reference reflectance", there is lack of antecedent basis for this limitation within the claims.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In regards to claim 1, line 8, because there are so many reflectance limitations (reflectance constant, reflectance at a second wavelength, and measured reflectance) it is not clear which reflectance "the reflectance" is referring to, making this claim confusing. Clarification is required.

In regards to claim 8, line 15, because there are so many reflectance limitations (reflectance constant, reflectance at a second wavelength, and measured reflectance) it is not clear which reflectance "the reflectance" is referring to, making this claim confusing. Clarification is required.

In regards to claim 15, line 14, because there are so many reflectance limitations (reflectance constant, reflectance at a second wavelength, and measured reflectance) it is not clear which reflectance "the reflectance" is referring to, making this claim confusing. Clarification is required.

In regards to claim 19, line 14, because there are so many reflectance limitations (reflectance constant, reflectance at a second wavelength, and measured reflectance) it is not clear which reflectance "the reflectance" is referring to, making this claim confusing. Clarification is required.

Claims, which are dependent from claims 1, 8, 15 and 19 inherit the problems of these claims, and are therefore also rejected under 35 U.S.C. 112, second paragraph.

For the purposes of applying art, "the reflectance" will be construed to mean the reflectance at the second wavelength.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-4, 8-11, and 15-22 are rejected under 35 U.S.C. 102(e) as being anticipated by Howard, III (US Pubs 20060/0139649).

In regards to claim 1, Howard discloses a method of correcting reflectance (abstract) comprising the steps of: A. determining a reflectance constant for a test product at a first wavelength for which reflectance does not substantially change with the presence of a test substance (equation 2, r_{IR}); B. with the test product loaded with the test substance, determining a reflectance at a second wavelength for

which signal-to-noise ratio is maximized (¶ 52 R) and determining a measured reflectance at the first wavelength (R_{IR}); and C. determining a corrected reflectance as the product of the reflectance with a ratio of the reflectance constant to the measured reflectance (¶s 53-54 and 56-57).

In regards to claim 2, the test substance is an analyte (¶s 3, 5 and 26).

In regards to claim 3, the test product is a test strip comprising a plurality of test pads (¶s 3, 5 and 26).

In regards to claim 4, the test product is a reagent cassette (¶s 3, 7 and 26).

In regards to claim 8, Howard discloses a reflectance-based system including reflectance correction (figs. 1-3b), the system comprising: A. transmitters (302) for transmitting signals at different wavelengths to a test product (290) and detectors configured for detecting reflectance at the different wavelengths from the test product (360); B. a set of storage devices configured for storing reflectance values (¶ 40; the measurements are stored, therefore, it is inherent that there is a storage device); C. a set of processors (fig. 5, 550) configured to execute a program configured to implement a method of correcting reflectance comprising the steps of: i) determining a reflectance constant for the test product at a first wavelength for which reflectance does not substantially change with the presence of a test substance (equation 2, r_{IR}); ii) with the test product loaded with the test substance, determining a reflectance at a second wavelength for which signal-to-noise ratio is maximized (¶ 52 R) and determining a measured reflectance at the first wavelength (R_{IR}); and iii) determining a corrected reflectance as the product of the reflectance with a ratio of the reflectance constant to the measured reflectance (¶s 53-54 and 56-57).

In regards to claim 9, the test substance is an analyte (¶s 3, 5 and 26).

In regards to claim 10, the test product is a test strip comprising a plurality of test pads (¶s 3, 5 and 26).

In regards to claim 11, the test product is a reagent cassette (¶s 3, 7 and 26).

In regards to claim 15, Howard discloses a computer program code embodying instructions for execution by at least one processor to perform a method for correcting reflectance in a reflectance-based device (figs. 1-3b) comprising transmitters (302) for transmitting signals at different wavelengths to a test product (290) and detectors configured for detecting reflectance at the different wavelengths from the test product (360), a set of storage devices configured for storing reflectance values (¶ 40; the measurements are stored, therefore, it is inherent that there is a storage device), the method comprising: A. determining a reflectance constant for a test product at a first wavelength for which reflectance does not substantially change with the presence of a test substance (equation 2, r_{IR}); B. with the test product loaded with the test substance, determining a reflectance at a second wavelength for which signal-to-noise ratio is maximized (¶ 52 R) and determining a measured reflectance at the first wavelength (R_{IR}); and C. determining a corrected reflectance as the product of the reflectance with a ratio of the reflectance constant to the measured reflectance (¶s 53-54 and 56-57).

In regards to claim 16, the test substance is an analyte (¶s 3, 5 and 26).

In regards to claim 17, the test product is a test strip comprising a plurality of test pads (¶s 3, 5 and 26).

In regards to claim 18, the test product is a reagent cassette (¶s 3, 7 and 26).

In regards to claim 19, Howard discloses a reflectance-based system including reflectance correction (figs. 1-3b), the system comprising: A. transmitters (302) for transmitting signals at different wavelengths to a test product (290) and detectors configured for detecting reflectance at the different wavelengths from the test product (360); B. a set of storage devices configured for storing reflectance values (¶ 40; the measurements are stored, therefore, it is inherent that there is a storage device); C. means for determining a reflectance constant for the test product at a first wavelength for which reflectance does not substantially change with the presence of a test substance (equation 2, r_{IR}); D. with the test product loaded with the test substance, means for determining a reflectance at a second wavelength for which

signal-to-noise ratio is maximized (¶ 52 R) and means for determining a measured reflectance at the first wavelength (R_{IR}); and E. means for determining a corrected reflectance as the product of the reflectance with a ratio of the reflectance constant to the measured reflectance (¶s 53-54 and 56-57).

In regards to claim 20, the test substance is an analyte (¶s 3, 5 and 26).

In regards to claim 21, the test product is a test strip comprising a plurality of test pads (¶s 3, 5 and 26).

In regards to claim 22, the test product is a reagent cassette (¶s 3, 7 and 26).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 5-7, and 12-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Howard, III (US Pubs 20060/0139649) in view of well known practices in the art.

In regards to claims 5-6 and 12-13, Howard discloses the method and system as described above. Howard is silent to the measured/reference reflectance being determined with a pulse scan at the second/first wavelength. However, the Examiner takes Official notice that it is well known in the art that the prior art reflectometers as described by Howard, with a plurality of LED's at different wavelengths, are used in pulse scanned mode for each LED, and therefore for each wavelength, in order to have each wavelength/LED beam impinge on a sample and be reflected by the sample sequentially so that a measurement can be made for each wavelength range. Therefore, it would have been obvious to one of ordinary skill at the time the invention was made to have Howard's method/system have the measured/reference reflectance be determined with a pulse scan at the second/first wavelength in order to

have each wavelength/LED beam impinge on a sample and be reflected by the sample sequentially so that a measurement can be made for each wavelength range.

In regards to claims 7 and 14, Howard discloses the method and system as described above. Howard is silent to the reference reflectance being determined before conditions relative to a concentration of the test substance substantially changes from the time the measured reflectance was determined. However, the examiner takes Official Notice that this is a very well known method of measuring a reference, and it is done in order to have the reference be measured in the same conditions as the actual measurement, in order to have the reference measurement be able to be used to remove all errors caused by the condition more precisely, thereby giving a more accurate measurement. Therefore, it would have been obvious to one of ordinary skill at the time the invention was made to have the reference reflectance be determined before conditions relative to a concentration of the test substance substantially changes from the time the measured reflectance was determined in order to have the reference measurement be able to be used to remove all the measurement variables more precisely, thereby giving a more accurate measurement.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kara E Geisel whose telephone number is **571 272 2416**. The examiner can normally be reached on Monday through Friday, 8am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gregory J. Toatley, Jr. can be reached on **571 272 2800 ext. 77**. The fax phone number for the organization where this application or proceeding is assigned is **571 273 8300**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kara E Geisel/
Patent Examiner,
Art Unit 2877

August 13, 2008